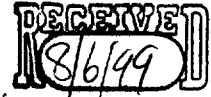




August 3, 1999



Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, DC 20204

RE: Ricola® Herbal Health™ Night Time Formula

To Whom It May Concern:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Ricola, Inc. ("Ricola"), Morris Plains, New Jersey 07950, hereby notifies the Food and Drug Administration that within the past 30 days the Company has begun marketing a dietary supplement with a label that bears statements of nutritional support. Ricola is the distributor of this product.

The dietary supplement for which the statements are made is Ricola® Herbal Health™ Night Time Formula. Per serving size of one tablet, the supplement contains: Valerian root standardized extract, 200 mg; Relaxing herbal blend, 100 mg (kava kava root standardized extract, hops strobile extract and Seville orange blossom); and Bio-enhancing herbal blend, 12.5 mg (extracts of hyssop, lemon balm leaf, peppermint leaf, sage leaf and thyme leaf).

The statements of nutritional support for this product read as follows:

- In scientific studies, valerian has been shown to improve the quality of sleep.
- Ricola® Herbal Health™ Night Time Formula combines prime European valerian with a relaxing blend of kava kava, calming hops, fragrant orange blossoms and healthful Ricola herbs.
- It's the natural way to help promote a restful night's sleep.

A copy of the outer package and inner-container label for the product is attached.

These statements are accompanied by the required disclaimer indicating that the statements have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure or prevent any disease.

Ricola USA, Inc.
51 Gibraltar Drive
Morris Plains, NJ 07950
Phone: 973-984-6811 ■ 800-323-9073
Fax: 973-984-6814
E-mail: info@ricolausa.com

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Ricola certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the DSHEA; and that the information contained in this notice is complete and accurate.

Sincerely,

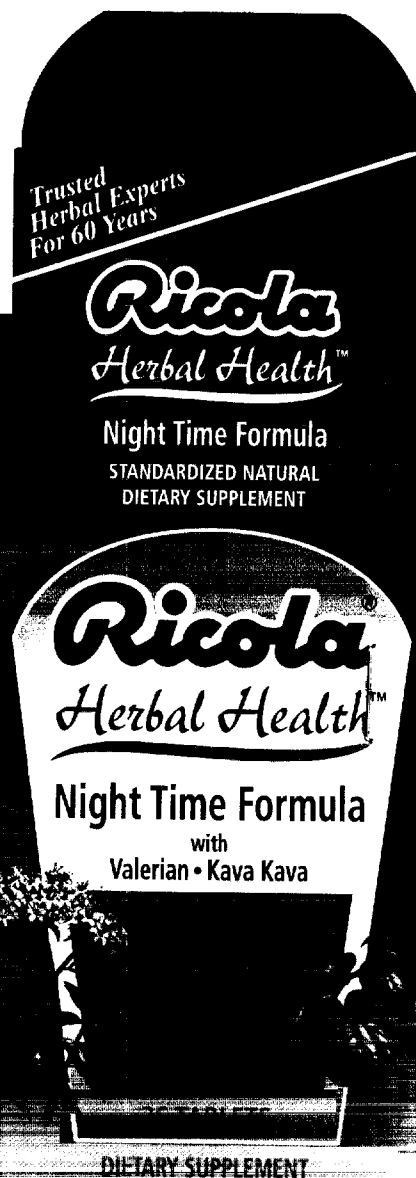
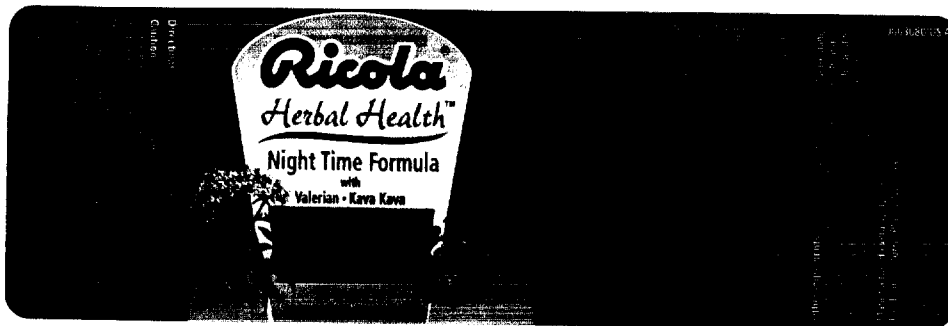
A handwritten signature in black ink, appearing to read "Dan Thomas", with a long horizontal flourish extending to the right.

Dan Thomas
President

Enclosure

Original plus two copies enclosed

Ricola® Herbal Health™ Night Time Formula



For more than sixty years the world has trusted the Ricola name for herbal products of the highest quality and purity. Today, the tradition continues with Ricola® Herbal Health™ supplements. Meticulously crafted by Swiss experts, these balanced formulas skillfully combine research-recommended levels of highly standardized botanicals. Each formula is further enhanced for optimum digestibility with an exclusive blend of healthful Ricola herbs.

Directions: Take one tablet shortly before bedtime.

Caution: Consult your health professional before using if you are pregnant, nursing a baby, or are taking any prescription medication. Keep out of the reach of children.

Store at 15–30 °C (59–86 °F) away from heat, light and moisture. Do not purchase if printed neckband seal of bottle is broken. This product contains herbal ingredients, which may have distinct natural odors.

In scientific studies, valerian has been shown to improve the quality of sleep. Ricola® Herbal Health™ Night Time Formula combines prime European valerian with a relaxing blend of kava kava, calming hops, fragrant orange blossoms and healthful Ricola herbs. It's the natural way to help promote a restful night's sleep.

Ricola® Herbal Health™ dietary supplements also available:

- Active Memory Formula
- Heart Formula
- Antioxidant Formula
- Prostate Formula
- Women's Formula
- Immune Formula
- Mood Formula

Other ingredients: dicalcium phosphate, cellulose, cellulose gum, vegetable stearic acid, silica, vegetable magnesium stearate and tablet coating (sucrose, calcium sulfate, calcium carbonate, gelatin, titanium dioxide, hydroxy magnesium silicate, vegetable resin, caramel color, riboflavin and vegetable wax).

Exclusively manufactured for:
Ricola Inc., Morris Plains, NJ 07950

For comments or questions
on Ricola herbal supplements,
call 1-800-323-9073, or visit us at
www.ricolausa.com.

The statements herein have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

